

What is claimed is:

1. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:2 (S1 isolate), SEQ ID NO:3 (JL isolate), SEQ ID NO:4 (RJL1 isolate), SEQ ID NO:5 (L2 isolate), and SEQ ID NO:6 (composite).

5

2. A biologically active fragment of the polypeptide of claim 1.

3. An isolated nucleic acid encoding the polypeptide of claim 1.

10

4. An isolated nucleic acid encoding the fragment of claim 2.

15

5. An isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of the nucleotide sequence of SEQ ID NO:8 (S1 coding sequence), the nucleotide sequence of SEQ ID NO:10 (JL coding sequence), the nucleotide sequence of SEQ ID NO:11 (RJL1 coding sequence), and the nucleotide sequence of SEQ ID NO:9 (L2 coding sequence).

6. An antibody that specifically binds the polypeptide of claim 1.

20

7. An antibody that specifically binds the fragment of claim 2.

25

8. An isolated nucleic acid consisting essentially of the nucleotide sequence of SEQ ID NO:12 (Primer 1), SEQ ID NO:13 (Primer 2), SEQ ID NO:14 (Primer 3), SEQ ID NO:15 (Primer 4), SEQ ID NO:16 (Primer 5), SEQ ID NO:17 (Primer 6), SEQ ID NO:18 (Primer 7), SEQ ID NO:19 (Primer 8), SEQ ID NO:20 (Primer 9), SEQ ID NO:21 (Primer 10), SEQ ID NO:22 (Primer 11), SEQ ID NO:23 (Primer 12), SEQ ID

NO:24 (Primer 13), SEQ ID NO:25 (Primer 14), SEQ ID NO:26 (Primer 15), SEQ ID NO:27 (Primer 16) or any combination thereof.

9. A composition comprising the polypeptide of claim 1 and a pharmaceutically acceptable carrier.

10. A composition comprising the fragment of claim 2 and a pharmaceutically acceptable carrier.

11. A composition comprising the nucleic acid of claim 3 and a pharmaceutically acceptable carrier.

12. A composition comprising the nucleic acid of claim 4 and a pharmaceutically acceptable carrier.

15

13. A composition comprising the nucleic acid of claim 5 and a pharmaceutically acceptable carrier.

14. A composition comprising the antibody of claim 6 and a pharmaceutically acceptable carrier.

15. A composition comprising the antibody of claim 7 and a pharmaceutically acceptable carrier.

25 16. A method of diagnosing infection by *Mycoplasma pneumoniae* in a subject,

comprising contacting a biological sample from the subject with the polypeptide of claim 1 under conditions whereby an antigen/antibody complex can form and detecting formation of an antigen/antibody complex, thereby diagnosing infection by *Mycoplasma pneumoniae* in the subject.

5

17. A method of diagnosing infection by *Mycoplasma pneumoniae* in a subject comprising contacting a biological sample from the subject with the polypeptide of claim 2 under conditions whereby an antigen/antibody complex can form and detecting formation of an antigen/antibody complex, thereby diagnosing infection by 10 *Mycoplasma pneumoniae* in the subject.

18. A method of diagnosing infection by *Mycoplasma pneumoniae* in a subject comprising contacting a biological sample from the subject with the antibody of claim 6 under conditions whereby an antigen/antibody complex can form and detecting 15 formation of an antigen/antibody complex, thereby diagnosing infection by *Mycoplasma pneumoniae* in the subject.

19. A method of diagnosing infection by *Mycoplasma pneumoniae* in a subject comprising contacting a biological sample from the subject with the antibody of claim 7 20 under conditions whereby an antigen/antibody complex can form and detecting formation of an antigen/antibody complex, thereby diagnosing infection by *Mycoplasma pneumoniae* in the subject.

20. A method of diagnosing infection by *Mycoplasma pneumoniae* in a 25 subject, comprising contacting a biological sample from the subject with the nucleic acid of any of claims 3, 4 or 5 under conditions whereby hybridization of nucleic acid molecules can occur and detecting a hybridization complex, thereby diagnosing

infection by *Mycoplasma pneumoniae* in the subject.

21. A kit for diagnosing an infection by *Mycoplasma pneumoniae* in a subject comprising the polypeptide of claim 1, the fragment of claim 2, the antibody of claim 6, 5 the nucleic acid of claims 3-5 and/or the antibody of claim 7.
22. A method of eliciting an immune response in a subject, comprising administering to the subject an effective amount of the polypeptide of claim 1.
- 10 23. A method of eliciting an immune response in a subject, comprising administering to the subject an effective amount of the fragment of claim 2.
24. A method of eliciting an immune response in a subject comprising administering to the subject an effective amount of the nucleic acid of claim 3.
- 15 25. A method of eliciting an immune response in a subject comprising administering to the subject an effective amount of the nucleic acid of claim 4.
26. A method of providing passive immunity to a subject, comprising 20 administering to the subject an effective amount of the antibody of claim 6.
27. A method of providing passive immunity to a subject, comprising administering to the subject an effective amount of the antibody of claim 7.
- 25 28. A method of treating or preventing infection by *Mycoplasma pneumoniae*

in a subject, comprising administering to the subject an effective amount of the polypeptide of claim 1.

29. A method of treating or preventing infection by *Mycoplasma pneumoniae*  
5 in a subject, comprising administering to the subject an effective amount of the fragment of claim 2.

30. A method of treating or preventing infection by *Mycoplasma pneumoniae* in a subject comprising administering to the subject an effective amount of the nucleic acid of any of claims 3, 4 or 5.  
10

31. A method of treating or preventing infection by *Mycoplasma pneumoniae* in a subject, comprising administering to the subject an effective amount of the antibody of claim 6.  
15

32. A method of treating or preventing infection by *Mycoplasma pneumoniae* in a subject, comprising administering to the subject an effective amount of the antibody of claim 7.  
20

33. A method of identifying a substance having the ability to inhibit the binding activity of the CARDs toxin comprising contacting the substance with the CARDs protein or a biologically active fragment thereof under conditions whereby binding can occur and detecting a decrease in the amount of binding in the presence of the substance as compared to a control amount of binding in the absence of the substance, thereby identifying a substance having the ability to inhibit the binding activity of the CARDs toxin.  
25

34. A method of identifying a substance having the ability to inhibit the translocating activity of the CARDs toxin, comprising contacting the substance with the CARDs toxin or a biologically active fragment thereof under conditions whereby translocation activity can occur and detecting a decrease in the amount of translocation activity in the presence of the substance as compared to a control amount of translocation activity in the absence of the substance, thereby identifying a substance having the ability to inhibit the translocating activity of the CARDs toxin.

10 35. A method of identifying a substance having the ability to enhance the immunogenic activity of the CARDs toxin, comprising contacting the substance with the CARDs toxin or an immunogenic fragment thereof under conditions whereby a measurable immune response can be elicited and detecting an increase in the amount of immune response in the presence of the substance, as compared to a control amount of immune response in the absence of the substance, thereby identifying a substance having the ability to enhance immunogenic activity of the CARDs toxin.

15 36. A method of identifying a substance having the ability to inhibit the ADP-ribosylating activity of the CARDs toxin, comprising contacting the substance with the CARDs toxin or biologically active fragment thereof under conditions whereby ADP ribosylation can occur and detecting a decrease in the amount of ADP ribosylation in the presence of the substance as compared to a control amount of ADP ribosylation in the absence of the substance, thereby identifying a substance having the ability to inhibit the ADP ribosylating activity of the CARDs toxin.

25

37. A method of identifying a substance having the ability to inhibit the cytopathology-inducing activity of the CARDs toxin, comprising contacting the substance with the CARDs toxin or biologically active fragment thereof under

conditions whereby cytopathology of target cells can be induced and detecting a decrease in the amount of cytopathology in the presence of the substance, as compared to a control amount of cytopathology in the absence of the substance, thereby identifying a substance having the ability to inhibit the cytopathology-inducing activity 5 of the CARDs toxin or biologically active fragment thereof.

38. A D1 domain of CARDs Toxin comprising the amino acid sequence of SEQ ID NO:69.

10 39. A D1 domain of CARDs Toxin comprising the amino acid sequence of SEQ ID NO:75.

40. A D2 domain of CARDs Toxin comprising the amino acid sequence of SEQ ID NO: 70.

15

41. A D3 domain of CARDs Toxin comprising the amino acid sequence of SEQ ID NO:71.

20

43. The nucleic acid of claim 42, wherein the nucleic acid comprises the nucleotide sequence of SEQ ID NO:74.

25

44. An antibody that specifically binds the domain of claims 38-41.

45. The antibody of claim 44, wherein the antibody is a monoclonal antibody.